IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: **Garvey et al**

Application No: **09/516,194** Group Art Unit: **1626**

Filed: **March 1, 2000** Examiner: **R. Gerstl**

For: **Nitrosated and Nitrosylated Prostaglandins, Compositions and Methods of Use**

Attorney Docket No: **102258.285**

#15 Petition

ATTN: GROUP 1600 TECHNOLOGY CENTER DIRECTOR
Assistant Commissioner of Patents
Washington, DC 20231

Petition from Restriction Requirement under 37 CFR § 1.144

Applicants Petition under 37 C.F.R. § 1.144 from the Examiner's final restriction requirement, election of species requirement, and misjoinder of inventions objection in the Office Action dated May 8, 2001, which was made final in the Office Action dated January 22, 2002.

I. The Restriction and Election of Species Requirements and Misjoinder of Invention Objection

In an Office Action dated May 8, 2001, the Examiner made a restriction requirement to claims 1-115 and requested Applicant to elect a single disclosed species. In particular, the Examiner restricted the invention as follows:

Group I	Claims 1-9	Compounds of Formula I
Group II	Claims 10-115	Compositions Comprising Compounds of Formula I

On June 8, 2001, Applicants traversed the restriction requirement and provisionally elected Group II drawn to compositions comprising a compound of Formula I and a vasoactive agent. Applicants traversed the election of species requirement and provisionally elected nitrosated prostaglandins (i.e., prostaglandins containing at least one $-NO_2$ group) as the species for the compound of Formula I; and phentolamine as the species for the vasoactive agent.

In the Office Action dated July 24, 2001, the Examiner maintained the restriction requirement and objected to claims 2-8, 10-17, 19-31, 33-40 and 104-106 as being directed to a

misjoinder of inventions. The Examiner indicated that the claims were examined to the extent they read on the elected species of the nitrosated prostaglandins (i.e., prostaglandins containing at least one -NO_2 group). *See* Office Action dated July 24, 2001, at Paragraph No. 1. The Examiner further indicated that the claims limited to the elected invention would be allowed. *See* Office Action dated July 24, 2001, at Paragraph No. 3. The Examiner did not make any rejections under 35 USC § 102 or § 103 against the elected species.

On October 24, 2001, Applicants requested examination of the other species that fell within the scope of the compound of Formula I pursuant to MPEP § 803.02. The other compounds that fall within the scope of the compound of Formula I include (i) nitrosated and nitrosylated prostaglandins and (ii) nitrosylated prostaglandins.

In the final Office Action dated January 22, 2002, the Examiner allowed claims 2-8, 10-17, 19-31,33-40 and 104-106 to the extent that they read on the elected species, i.e., the nitrosated prostaglandins (i.e., prostaglandins that contain at least one -NO_2 group). *See* Office Action dated January 22, 2002, at Paragraph No. 1. The Examiner objected to the claims as being directed to a misjoinder of inventions of nitro (nitrosated prostaglandins, i.e., prostaglandins that contain at least one -NO_2 group) and nitroso (nitrosylated prostaglandins, i.e., prostaglandins that contain at least one -NO group)). *See* Office Action dated January 22, 2002, at Paragraph No. 2. The Examiner, however, failed to mention or consider nitro **and** nitroso substituted prostaglandins that fall within the scope of the compound of Formula I.

A copy of the pending claims is attached hereto as Appendix 1.

This Petition is timely filed: Applicants traversed and requested reconsideration of the restriction requirement, the election of species requirement, and the misjoinder of inventions objection.

II Request for Reconsideration of the Examiner's Decision

Applicants respectfully request reconsideration and reversal of the Examiner's decision to the extent the Examiner objects to pending claims 2-8, 10-17, 19-31, 33-40 and 104-106 as being directed to misjoinder of inventions.

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Pending claims 1-8, 10-17, 19-31, 33-40 and 104-106 all fall within the scope of Group II of the Examiner's Restriction Requirement dated May 8, 2001. All the pending claims are directed to compositions and kits comprising a compound of Formula I and their methods of use for the treatment of sexual dysfunctions.

The pending claims are all directed to the same invention. Claim 2 recites compounds of Formula I that are nitrosated prostaglandins (i.e., prostaglandins that contain a $-NO_2$ group); nitrosylated prostaglandins (i.e., prostaglandins that contain a -NO group), and nitrosated and nitrosylated prostaglandins (i.e., prostaglandins that contain a $-NO_2$ group and a -NO group).

Since the Examiner allowed claims directed to the elected species, i.e., nitrosated prostaglandins (i.e., prostaglandins that contain a $-NO_2$ group), Applicants respectfully submit that the Examiner is required to consider the compounds of Formula I to the extent they cover nitrosated and nitrosylated prostaglandins (i.e., prostaglandins that contain a $-NO_2$ group and a -NO group); and to the extent they cover nitrosylated prostaglandins (i.e., prostaglandins that contain a -NO group). Moreover, claim 1 is directed to compounds that are nitrosylated prostaglandins and is encompassed within the scope of claim 2.

It is unfair and contrary to the provisions of MPEP § 803.02 for the Examiner to refuse to consider compounds that contain both a $-NO_2$ group and a -NO group, or compounds that contain a -NO group. Contrary to the Examiner's assertion, the compound of Formula I is not limited to nitro and nitroso compounds. The compound of Formula I covers (i) nitro-substituted prostaglandins, (ii) nitroso-substituted prostaglandins and (iii) nitro- and nitroso-substituted prostaglandins.

MPEP § 803.02 states that upon an indication of the allowability of the elected species, the examination of additional species will be conducted. In particular, "should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended [to the non-elected species]....The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim."

The Examiner's refusal to examine the additional species in claims 1-8, 10-17, 19-31, 33-40 and 104-106 in the pending application is improper.

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Applicants respectfully request that the Examiner be required to consider nitrosated and nitrosylated prostaglandins (i.e., prostaglandins that contain a $-NO_2$ group and a -NO group), and nitrosylated prostaglandins (i.e., prostaglandins that contain an -NO group). Again, the Examiner allowed the claims to the extent that they read on nitrosated prostaglandins (i.e., prostaglandins that contain a $-NO_2$ group).

Applicants respectfully request the rejoinder and consideration of the additional species in pending claims 1-8, 10-17, 19-31, 33-40 and 104-106.

The Commissioner is authorized to charge any necessary fees for consideration of this Petition to Deposit Account No. 08-0219.

Respectfully submitted

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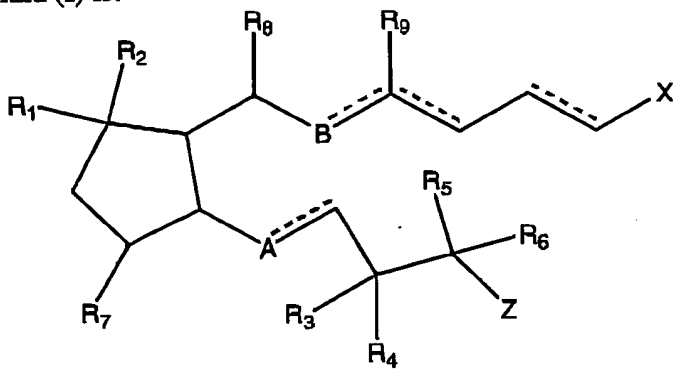
Appendix 1 Pending Claims

What is claimed is:

1. A prostaglandin comprising at least one NO group or a pharmaceutically acceptable salt thereof.

2. A compound of formula (I) or a pharmaceutically acceptable salt thereof, wherein the compound of formula (I) is:



(I)

wherein the dotted lines indicate a single or a double bond;

R_1 is $-OD_1$ or –Cl;

R_2 and R_8 are a hydrogen ; or R_1 and R_2 taken together are $=CH_2$ or =O;

R_3 and R_4 are each independently a hydrogen, $-OD_1$ or $-CH_3$;

R_5 and R_6 are each independently a hydrogen, $-OD_1$, $-CH_3$, $-OCH_3$ or $-CH=CH_2$;

R_7 is a hydrogen or $-OD_1$;

R_9 is hydrogen or absent when the carbon to which it is attached is the central carbon of an allene functionality; or R_8 and R_9 taken together with the chain to which they are attached form a substituted benzene ring with the proviso that R_1 is an oxygen atom which is attached to the carbon atom at the position of the benzene ring defined by B;

A is –CH=, $-CH_2$, -S-, or -O-;

B is –CH=, $-CH_2$, -S-, or –C(O)-;

X is $-CH_2OR_{11}$, $-C(O)OR_{11}$ or $-C(O)N(D_1)R_{12}$;

R_{11} is D_1, a lower alkyl group, or

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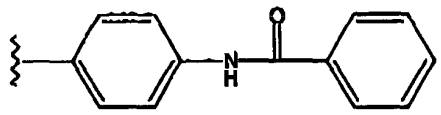
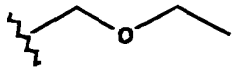


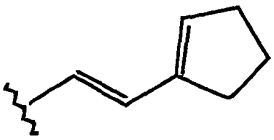
R_{12} is $-S(O)_2CH_3$ or $-C(O)CH_3$;

Z is (a) an ethyl, (b) a butyl, (c) a hexyl, (d) a benzyl,

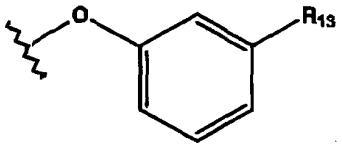
(e)



(f)

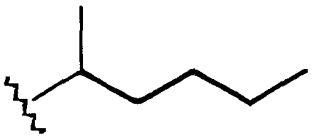


(g)



(h)

or



R_{13} is a hydrogen or –Cl;

D_1 is a hydrogen or D; with the proviso that at least one D_1 in formula (I) must be D;

D is Q or K;

Q is -NO or $-NO_2$;

K is $-W_a-E_b-(C(R_e)(R_f))_p-E_c-(C(R_e)(R_f))_x-W_d-(C(R_e)(R_f))_y-W_i-E_j-W_g-(C(R_e)(R_f))_z-T-Q$;

with the proviso that when X is $-C(O)OD_1$ and D_1 is K, then K is not an alkyl, branched alkyl or cycloalkyl mononitrate; a benzoic acid substituted benzyloxy mononitrate; the regioisomeric esters of glycerol dinitrate and oligomers thereof;

a, b, c, d, g, i and j are each independently an integer from 0 to 3;

p, x, y and z are each independently an integer from 0 to 10;

W at each occurrence is independently -C(O)-, -C(S)-, -T-, $-(C(R_e)(R_f))_h-$, an alkyl group, an aryl group, a heterocyclic ring, an arylheterocyclic ring, or $-(CH_2CH_2O)_q-$;

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E at each occurrence is independently -T-, an alkyl group, an aryl group, $-(C(R_e)(R_f))_h-$, a heterocyclic ring, an arylheterocyclic ring, or $-(CH_2CH_2O)_q-$;

h is an integer form 1 to 10;

q is an integer from 1 to 5;

R_e and R_f are each independently a hydrogen, an alkyl, a cycloalkoxy, a halogen, a hydroxy, an hydroxyalkyl, an alkoxyalkyl, an arylheterocyclic ring, an alkylaryl, a cycloalkylalkyl, a heterocyclicalkyl, an alkoxy, a haloalkoxy, an amino, an alkylamino, a dialkylamino, an arylamino, a diarylamino, an alkylarylamino, an alkoxyhaloalkyl, a haloalkoxy, a sulfonic acid, a sulfonic ester, an alkylsulfonic acid, an arylsulfonic acid, an arylalkoxy, an alkylthio, an arylthio, a cycloalkylthio, a cycloalkenyl, a cyano, an aminoalkyl, an aminoaryl, an aryl, an arylalkyl, an alkylaryl, a carboxamido, a alkylcarboxamido, an arylcarboxamido, an amidyl, a carboxyl, a carbamoyl, a carbamate, an alkylcarboxylic acid, an arylcarboxylic acid, an alkylcarbonyl, an arylcarbonyl, an ester, a carboxylic ester, an alkylcarboxylic ester, an arylcarboxylic ester, a haloalkoxy, a sulfonamido, an alkylsulfonamido, an arylsulfonamido, a sulfonic ester, a urea, a phosphoryl, a nitro, -T-Q , or $(C(R_e)(R_f))_k$-T-Q, or R_e and R_f taken together with the carbons to which they are attached form a carbonyl, a methanthial, a heterocyclic ring, a cycloalkyl group or a bridged cycloalkyl group;

k is an integer from 1 to 3;

T at each occurrence is independently a covalent bond, a carbonyl, an oxygen, $-S(O)_o-$ or $-N(R_a)R_i-$;

o is an integer from 0 to 2;

R_a is a lone pair of electrons, a hydrogen or an alkyl group;

R_i is a hydrogen, an alkyl, an aryl, an alkylcarboxylic acid, an arylcarboxylic acid, an alkylcarboxylic ester, an arylcarboxylic ester, an alkylcarboxamido, an arylcarboxamido, an alkylaryl, an alkylsulfinyl, an alkylsulfonyl, an arylsulfinyl, an arylsulfonyl, a sulfonamido, a carboxamido, a carboxylic ester, an amino alkyl, an amino aryl, $-CH_2-C(T-Q)(R_e)(R_f)$, or $-(N_2O_2-)^-\bullet M^+$, wherein M^+ is an organic or inorganic cation; with the proviso that when R_i is $-CH_2-C(T-Q)(R_e)(R_f)$ or $-(N_2O_2)^-\bullet M^+$, or R_e or R_f are T-Q or $(C(R_e)(R_f))_k$-T-Q, then the "-T- Q" subgroup can be a hydrogen, an alkyl, an alkoxy, an alkoxyalkyl, an aminoalkyl, a hydroxy, a heterocyclic ring or an aryl group.

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3. The compound of claim 2, wherein the compound comprising at least one NO group, at least one NO_2 group, or at least one NO and NO_2 group is a nitrosated arbaprostil, a nitrosylated arbaprostil, a nitrosated and nitrosylated arbaprostil, a nitrosated alprostadil, a nitrosylated alprostadil, a nitrosated and nitrosylated alprostadil, a nitrosated beraprost, a nitrosylated beraprost, a nitrosated and nitrosylated beraprost, a nitrosated carboprost, a nitrosylated carboprost, a nitrosated and nitrosylated carboprost, a nitrosated cloprostenol, a nitrosylated cloprostenol, a nitrosated and nitrosylated cloprostenol, a nitrosated dimoxaprost, a nitrosylated dimoxaprost, a nitrosated and nitrosylated dimoxaprost, a nitrosated enprostil, a nitrosylated enprostil, a nitrosated and nitrosylated enprostil, a nitrosated enisoprost, a nitrosylated enisoprost, a nitrosated and nitrosylated enisoprost, a nitrosated fluprostenol, a nitrosylated fluprostenol, a nitrosated and nitrosylated fluprostenol, a nitrosated fenprostalene, a nitrosylated fenprostalene, a nitrosated and nitrosylated fenprostalene, a nitrosated gemeprost, a nitrosylated gemeprost, a nitrosated and nitrosylated gemeprost, a nitrosated latanaprost, a nitrosylated latanaprost, a nitrosated and nitrosylated latanaprost, a nitrosated limaprost, a nitrosylated limaprost, a nitrosated and nitrosylated limaprost, a nitrosated meteneprost, a nitrosylated meteneprost, a nitrosated and nitrosylated meteneprost, a nitrosated mexiprostil, a nitrosylated mexiprostil, a nitrosated and nitrosylated mexiprostil, a nitrosated misoprostol, a nitrosylated misoprostol, a nitrosated and nitrosylated misoprostol, a nitrosated misoprost, a nitrosylated misoprost, a nitrosated and nitrosylated misoprost, a nitrosated misoprostol acid, a nitrosylated misoprostol acid, a nitrosated and nitrosylated misoprostol acid, a nitrosated nocloprost, a nitrosylated nocloprost, a nitrosated and nitrosylated nocloprost, a nitrosated ornoprostil, a nitrosylated ornoprostil, a nitrosated and nitrosylated ornoprostil, a nitrosated prostalene, a nitrosylated prostalene, a nitrosated and nitrosylated prostalene, a nitrosated PGE_1, a nitrosylated PGE_1, a nitrosated and nitrosylated PGE_1, a nitrosated PGE_2, a nitrosylated PGE_2, a nitrosated and nitrosylated PGE_2, a nitrosated PGF_1, a nitrosylated PGF_1, a nitrosated and nitrosylated PGF_1, a nitrosated $PGF_{2\alpha}$, a nitrosylated $PGF_{2\alpha}$, a nitrosated and nitrosylated $PGF_{2\alpha}$, a nitrosated rioprostil, a nitrosylated rioprostil, a nitrosated and nitrosylated rioprostil, a nitrosated rosaprostol, a nitrosylated rosaprostol, a nitrosated and nitrosylated rosaprostol, a nitrosated remiprostol, a nitrosylated remiprostol, a nitrosated and nitrosylated remiprostol, a nitrosated sulprostone, a nitrosylated sulprostone, a nitrosated and nitrosylated sulprostone, a nitrosated trimoprostil, a nitrosylated trimoprostil, a nitrosated and nitrosylated trimoprostil, a

nitrosated tiprostanide, a nitrosylated tiprostanide, a nitrosated and nitrosylated tiprostanide, a nitrosated unoprostone, a nitrosylated unoprostone, a nitrosated and nitrosylated unoprostone, a nitrosated viprostol, a nitrosylated viprostol, a nitrosated and nitrosylated viprostol or a mixture thereof.

4. A composition comprising the compound of claim 2 and a pharmaceutically acceptable carrier.

5. A method for treating a sexual dysfunction in a patient in need thereof comprising administering to the patient a therapeutically effective amount of the composition of claim 4.

6. The method of claim 5, wherein the patient is female.

7. The method of claim 5, wherein the patient is male.

8. The method of claim 5, wherein the composition is administered orally, by intracavernosal injection, by transurethral application, or by transdermal application.

10. The composition of claim 4, further comprising at least one vasoactive agent or a pharmaceutically acceptable salt thereof.

11. The composition of claim 10, wherein the vasoactive agent is a potassium channel activator, a calcium channel blocker, an α-blocker, a β-blocker, a phosphodiesterase inhibitor, adenosine, an ergot alkaloid, a vasoactive intestinal peptide, a dopamine agonist, an opioid antagonist, an endothelin antagonist or a mixture thereof.

12. The composition of claim 10, wherein the vasoactive agent is an α-blocker or a phosphodiesterase inhibitor.

13. The composition of claim 12, wherein the α-blocker is phentolamine, prazosin, doxazosin, terazosin, yohimbine or moxisylyte and the phosphodiesterase inhibitor is papaverine, zaprinast, sildenafil or IC 351, or a mixture thereof.

14. A method for treating a sexual dysfunction in a patient in need thereof comprising administering to the patient a therapeutically effective amount of the composition of claim 10.

15. The method of claim 14, wherein the patient is female.

16. The method of claim 14, wherein the patient is male.

17. The method of claim 14, wherein the composition is administered orally, by intracavernosal injection, by transurethral application or by transdermal application.

19. A composition comprising at least one compound of claim 2 or a pharmaceutically acceptable salt thereof, and at least one compound that donates, transfers or

releases nitric oxide, or induces the production of endogenous nitric oxide or endothelium-derived relaxing factor, or is a substrate for nitric oxide synthase.

20. The composition of claim 19, further comprising a pharmaceutically acceptable carrier.

21. The composition of claim 19, wherein the compound that donates, transfers, or releases nitric oxide, or induces the production of endogenous nitric oxide or endothelium-derived relaxing factor or is a substrate for nitric oxide synthase is an S-nitrosothiol.

22. The composition of claim 21, wherein the S-nitrosothiol is S-nitroso-N-acetylcysteine, S-nitroso-captopril, S-nitroso-N-acetylpenicillamine, S-nitroso-homocysteine, S-nitroso-cysteine or S-nitroso-glutathione.

23. The composition of claim 21, wherein the S-nitrosothiol is:

(i) $HS(C(R_e)(R_f))_mSNO$;

(ii) $ONS(C(R_e)(R_f))_mR_e$; and

(iii) $H_2N\text{-}CH(CO_2H)\text{-}(CH_2)_m\text{-}C(O)NH\text{-}CH(CH_2SNO)\text{-}C(O)NH\text{-}CH_2\text{-}CO_2H$;

wherein m is an integer from 2 to 20; R_e and R_f are each independently a hydrogen, an alkyl, a cycloalkoxy, a halogen, a hydroxy, an hydroxyalkyl, an alkoxyalkyl, an arylheterocyclic ring, an alkylaryl, a cycloalkylalkyl, a heterocyclicalkyl, an alkoxy, a haloalkoxy, an amino, an alkylamino, a dialkylamino, an arylamino, a diarylamino, an alkylarylamino, an alkoxyhaloalkyl, a haloalkoxy, a sulfonic acid, a sulfonic ester, an alkylsulfonic acid, an arylsulfonic acid, an arylalkoxy, an alkylthio, an arylthio, a cycloalkylthio, a cycloalkenyl, a cyano, an aminoalkyl, an aminoaryl, an aryl, an arylalkyl, an alkylaryl, a carboxamido, a alkylcarboxamido, an arylcarboxamido, an amidyl, a carboxyl, a carbamoyl, a carbamate, an alkylcarboxylic acid, an arylcarboxylic acid, an alkylcarbonyl, an arylcarbonyl, an ester, a carboxylic ester, an alkylcarboxylic ester, an arylcarboxylic ester, a haloalkoxy, a sulfonamido, an alkylsulfonamido, an arylsulfonamido, a sulfonic ester, a urea, a phosphoryl, a nitro, -T-Q , or $(C(R_e)(R_f))_k$-T-Q, or R_e and R_f taken together with the carbons to which they are attached form a carbonyl, a methanthial, a heterocyclic ring, a cycloalkyl group or a bridged cycloalkyl group; Q is -NO or $-NO_2$; and T is independently a covalent bond, a carbonyl, an oxygen, $-S(O)_o-$ or $-N(R_a)R_i-$, wherein o is an integer from 0 to 2, R_a is a lone pair of electrons, a hydrogen or an alkyl group; R_i is a hydrogen, an alkyl, an aryl, an alkylcarboxylic acid, an aryl carboxylic acid, an alkylcarboxylic ester, an arylcarboxylic ester, an alkylcarboxamido, an arylcarboxamido, an

alkylaryl, an alkylsulfinyl, an alkylsulfonyl, an arylsulfinyl, an arylsulfonyl, a sulfonamido, a carboxamido, a carboxylic ester, an amino alkyl, an amino aryl, $-CH_2-C(T-Q)(R_e)(R_f)$, or $-(N_2O_2-)^-\bullet M^+$, wherein M^+ is an organic or inorganic cation; with the proviso that when R_i is $-CH_2-C(T-Q)(R_e)(R_f)$ or $-(N_2O_2-)\bullet M^+$; then "-T-Q" can be a hydrogen, an alkyl group, an alkoxyalkyl group, an aminoalkyl group, a hydroxy group or an aryl group.

24. The composition of claim 19, wherein the compound that donates, transfers, or releases nitric oxide, or induces the production of endogenous nitric oxide or endothelium-derived relaxing factor, or is a substrate for nitric oxide synthase, is L-arginine, L-homoarginine, N-hydroxy-L-arginine, nitrosated L-arginine, nitrosylated L-arginine, nitrosated N-hydroxy-L-arginine, nitrosylated N-hydroxy-L-arginine, citrulline, ornithine, glutamine, lysine, polypeptides comprising at least one of these amino acids or inhibitors of the enzyme arginase.

25. The composition of claim 19, wherein the compound that donates, transfers, or releases nitric oxide, or induces the production of endogenous nitric oxide or endothelium-derived relaxing factor, or is a substrate for nitric oxide synthase is:

(i) a compound that comprises at least one ON-O-, ON-N- or ON-C- group;

(ii) a compound that comprises at least one O_2N-O-, O_2N-N-, O_2N-S- or $-O_2N-C-$ group;

(iii) a N-oxo-N-nitrosoamine having the formula: $R^1R^2-N(O-M^+)-NO$, wherein R^1 and R^2 are each independently a polypeptide, an amino acid, a sugar, an oligonucleotide, a straight or branched, saturated or unsaturated, aliphatic or aromatic, substituted or unsubstituted hydrocarbon, or a heterocyclic group, and M^+ is an organic or inorganic cation.

26. The composition of claim 25, wherein the compound comprising at least one ON-O-, ON-N- or ON-C- group is an ON-O-polypeptide, an ON-N-polypepetide, an ON-C-polypeptide, an ON-O-amino acid, an ON-N-amino acid, an ON-C-amino acid, an ON-O-sugar, an ON-N-sugar, an ON-C-sugar, an ON-O-oligonucleotide, an ON-N-oligonucleotide, an ON-C-oligonucleotide, a straight or branched, saturated or unsaturated, substituted or unsubstituted, aliphatic or aromatic ON-O-hydrocarbon, a straight or branched, saturated or unsaturated, substituted or unsubstituted, aliphatic or aromatic ON-N-hydrocarbon, a straight or branched, saturated or unsaturated, substituted or unsubstituted, aliphatic or aromatic ON-C-hydrocarbon, an ON-O-heterocyclic compound, an ON-N-heterocyclic compound or a ON-C-heterocyclic compound.

27. The composition of claim 25, wherein compound comprising at least one O_2N-O-, O_2N-N-, O_2N-S- or O_2N-C- group is an O_2N-O-polypeptide, an O_2N-N-polypeptide, an O_2N-S-polypeptide, an O_2N-C-polypeptide, an O_2N-O-amino acid, O_2N-N-amino acid, O_2N-S-amino acid, an O_2N-C-amino acid, an O_2N-O-sugar, an O_2N-N-sugar, O_2N-S-sugar, an O_2N-C-sugar, an O_2N-O-oligonucleotide, an O_2N-N-oligonucleotide, an O_2N-S-oligonucleotide, an O_2N-C-oligonucleotide, a straight or branched, saturated or unsaturated, aliphatic or aromatic, substituted or unsubstituted O_2N-O-hydrocarbon, a straight or branched, saturated or unsaturated, aliphatic or aromatic, substituted or unsubstituted O_2N-N-hydrocarbon, a straight or branched, saturated or unsaturated, aliphatic or aromatic, substituted or unsubstituted O_2N-S-hydrocarbon, a straight or branched, saturated or unsaturated, aliphatic or aromatic, substituted or unsubstituted O_2N-C-hydrocarbon, an O_2N-O-heterocyclic compound, an O_2N-N-heterocyclic compound, an O_2N-S-heterocyclic compound or an O_2N-C-heterocyclic compound.

28. A method for treating a sexual dysfunction in a patient in need thereof comprising administering to the patient a therapeutically effective amount of the composition of claim 19.

29. The method of claim 28, wherein the patient is female.

30. The method of claim 28, wherein the patient is male.

31. The method of claim 28, wherein the composition is administered orally, by intracavernosal injection, by transurethral application or by transdermal application.

33. The composition of claim 19, further comprising at least one vasoactive agent or a pharmaceutically acceptable salt thereof.

34. The composition of claim 33, wherein the vasoactive agent is a potassium channel activator, a calcium channel blocker, an □□blocker, a □□blocker, a phosphodiesterase inhibitor, adenosine, an ergot alkaloid, a vasoactive intestinal peptide, a dopamine agonist, an opioid antagonist, an endothelin antagonist or a mixture thereof.

35. The composition of claim 34, wherein the vasoactive agent is an α-blocker or a phosphodiesterase inhibitor.

36. The composition of claim 35, wherein the α-blocker is phentolamine, prazosin, doxazosin, terazosin, yohimbine or moxisylyte and the phosphodiesterase inhibitor is papaverine, zaprinast, sildenafil or IC 351, or a mixture thereof.

37. A method for treating a sexual dysfunction in a patient in need thereof comprising administering to the patient a therapeutically effective amount of the composition of claim 33.

Appendix 1 – Pending Claims
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38. The method of claim 37, wherein the patient is female.

39. The method of claim 37, wherein the patient is male.

40. The method of claim 37, wherein the composition is administered orally, by intracavernosal injection, by transurethral application or by transdermal application.

104. A kit comprising at least one compound of claim 2 and at least one compound that donates, transfers or releases nitric oxide, or induces the production of endogenous nitric oxide or endothelium-derived relaxing factor, or is a substrate for nitric oxide synthase.

105. The kit of claim 104, wherein the compound of claim 2 and the at least one compound that donates, transfers or releases nitric oxide, induces the production of endogenous nitric oxide or endothelium-derived relaxing factor, or is a substrate for nitric oxide synthase are separate components in the kit or are in the form of a composition in the kit.

106. The kit of claim 104, further comprising at least one vasoactive agent.